IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
RICHMOND DIVISION

RENEGADE TOBACCO COMPANY, INC., *et al*.	)	
Plaintiffs,	)	
v.	)	Civ. No. 3:10-cv-265-HEH
U.S. FOOD AND DRUG ADMINISTRATION, *et al*.,	)	
Defendants.	)	

DEFENDANTS' OPPOSITION TO
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Defendants, the United States Food and Drug Administration and Commissioner Margaret Hamburg (collectively, "FDA"), respectfully submit this brief in opposition to plaintiffs' motion for a preliminary injunction.

Plaintiffs challenge the constitutionality of an FDA regulation, published on March 19, 2010, that precludes tobacco manufacturers from using the trade or brand name of a nontobacco product. *See* 21 C.F.R. § 1140.16(a); 75 Fed. Reg. 13225 (March 19, 2010). Their challenge focuses in large part on disparities created by a "grandfather clause" that exempts products that were being marketed in the United States on January 1, 1995, from the regulation.

FDA recognized, prior to the commencement of this litigation, the concerns created by this provision, *see* 75 Fed. Reg. 13226, and has already announced its intention to revise the regulation and to issue a Notice of Proposed Rulemaking in September 2010. *See* Exhibit A (Office of Management and Budget announcement). On May 4, 2010, FDA issued a guidance document that further explained that it does not intend to enforce the regulation during the reconsideration process as long as the trade or brand name of the tobacco product was registered or the product was marketed before June 22, 2009, the date of the enactment of the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"). *See* 75 Fed. Reg. 25271 ("the Guidance") (plaintiffs' Exhibit A). It is not disputed that plaintiffs' products fall within that category. *See* Pl. Mem. 9. In a further attempt to allay plaintiffs' concerns, on May 6, 2010, FDA wrote to plaintiffs' counsel and stated that it would not enforce the regulation without (a) first withdrawing the Guidance by notice published in the Federal Register and (b) issuing a warning letter to the potential subject of the enforcement action. *See* Exhibit B.

Although the regulation is not now being enforced against plaintiffs, may never be enforced against them, and will not in any event be enforced against them without publication of a notice withdrawing the Guidance and the issuance of a warning letter, plaintiffs seek "a preliminary injunction barring enforcement of the

Product Name Restriction, 21 CFR 1140.16(a), pending the final resolution of this case[.]" Complaint p. 27. The motion should be denied. The challenged regulation is under reconsideration. Plaintiffs have already received written assurance from the government that it does not currently intend to take action against them or their products under the challenged regulation and that it will not reverse course without additional written notice.

A preliminary injunction may not be issued unless a plaintiff makes a "clear showing that it will likely succeed on the merits" and a "a clear showing that it is likely to be irreparably harmed absent preliminary relief." *Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 346, 347 (4th Cir. 2009), *vacated on other grounds*, No. 09-724, 2010 WL 1641299 (S. Ct. April 26, 2010). The harm must be "neither remote nor speculative, but actual and imminent." *Scotts Co. v. United Industries Corp.*, 315 F.3d 264, 283 (4th Cir. 2002). Plaintiffs cannot satisfy either of these requirements.

Plaintiffs have no likelihood of success on the merits because they cannot establish a ripe controversy. The regulation that plaintiffs challenge is under reconsideration and FDA has made clear that it does not intend to enforce it against plaintiffs while it is being reconsidered. Strikingly, plaintiffs' motion papers fail to acknowledge that the agency is revisiting the regulation of which

they complain and that the reconsideration process may make the regulation altogether inapplicable to their products.

Nor can plaintiffs establish the imminent irreparable harm that is a prerequisite to a preliminary injunction. Plaintiffs' insistence that FDA might "at any time" change its position, Pl. Mem. 23, disregards the purpose of the non-enforcement policy, which is to preserve the *status quo* while the regulation is being reconsidered. In addition, this assertion ignores FDA's explicit written representation that, consistent with its usual practice in issuing guidance, it would not alter its position without first providing notice in the Federal Register and an advance warning to affected parties. *See* Exhibit B.

In pressing their unfounded request for immediate, interim relief, plaintiffs ask the Court to address constitutional issues that may well be avoided entirely if FDA amends its regulation. Their request for judicial intervention is premature in the extreme. Plaintiffs seek an advisory opinion in advance of the agency's own reconsideration of the relevant questions. Plaintiffs' request should be denied.

BACKGROUND

A brief review of the background of the challenged regulation is required in order to understand the present posture of FDA proceedings.

A. The challenged provision is part of comprehensive regulations first issued by FDA in 1996 that sought to reduce smoking among adolescents, the age

group that provides the vast majority of new smokers. *See* 21 C.F.R. Part 897 (1997) ("the 1996 FDA rule").[1] Among other restrictions, the 1996 FDA rule barred the use of a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product unless the trade or brand name was on both the tobacco product and a nontobacco product sold in the United States on January 1, 1995. *Id*. § 897.16(a).[2]

The restrictions in the 1996 FDA rule sought to eliminate the elements of marketing and advertising "that resonate most strongly with the needs of those under 18 to establish an appropriate image and to create a sense of acceptance and belonging." 61 Fed. Reg. 44396, 44444 (1996). FDA explained that the "use of

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[1] As the Supreme Court has recognized, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 161 (2000). The Court observed that "FDA characterized smoking as 'a pediatric disease,'" *id*. at 135 (citing 61 Fed. Reg. 44396, 44421 (1996)), "because 'one out of every three young people who become regular smokers ... will die prematurely as a result.'" *Ibid*. (citing 61 Fed. Reg. at 44399).

[2] Other provisions of the 1996 FDA rule restricted the offering of gifts to reward tobacco purchases, 21 C.F.R. § 897.34(b) (1997); the sponsorship of athletic, social, and cultural events in the brand name of a tobacco product, *id*. § 897.34(c); the distribution of merchandise bearing the name or logo of a tobacco brand, *id*. § 897.34(a); the use of color and imagery in tobacco advertising, *id*. § 897.32(a); the advertising of tobacco products in outdoor areas within 1,000 feet of a public playground, public park, or school, *id*. § 897.30(b); and the use of tobacco-product vending machines or self-service displays (except if located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time), *id*. § 897.16(c).

nontobacco trade names has particular appeal" in this regard. *Ibid*. "If a firm could use a popular nontobacco product trade name and put it on a tobacco product, the firm could attempt to exploit the imagery or consumer identification attached to the nontobacco product to make the tobacco appeal to young people." *Ibid*.

The tobacco industry challenged the 1996 rule before it became effective, and the rule was ultimately held invalid on statutory jurisdictional grounds in *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120 (2000). Although the Supreme Court found that FDA, in its rulemaking, had amply demonstrated the enormous public health threat posed by tobacco use, *id*. at 161, it concluded that Congress had not given FDA authority to regulate cigarettes and smokeless tobacco products as customarily marketed. *Id*. at 126.

B. In 2009, Congress enacted legislation that supplied the statutory authority that the Supreme Court found wanting in *Brown & Williamson*. The Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776, vests FDA with authority to regulate tobacco products, *see* 21 U.S.C. § 387a, requires new and more prominent health warnings on cigarettes and smokeless tobacco products, *see* 15 U.S.C. § 1333, 4402, and restricts the manner in which tobacco products may be marketed and advertised. *See generally Commonwealth Brands v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010)

(addressing constitutional challenges to the Tobacco Control Act), *appeals pending*, Nos. 10-5234 & 10-5235 (6th Cir.).

As particularly relevant here, the Tobacco Control Act directed FDA to issue a rule identical to the 1996 FDA rule (with specified exceptions not relevant here), *see* 21 U.S.C. § 387a-1, and provided that the reissued rule shall become effective on the date that is 1 year after the date of enactment of this Act, *i.e.*, on June 22, 2010. *See id*. § 387a-1(a)(2)(F). Congress provided, however, that FDA may amend the reissued rule through notice and comment rulemaking — but only after the original rule was reissued. *Id*. § 387a-1(a)(2)-(4).

C. As required by the Tobacco Control Act, on March 19, 2010, FDA published a final rule identical in its provisions to the regulation issued by FDA in 1996 (with specified exceptions not relevant here). *See* 75 Fed. Reg. 13225. At the same time, however, FDA recognized the concerns created by re-issuance of the trade or brand name restriction in its original form, and noted that it was reviewing the regulation to determine what changes might be appropriate. *Id*. at 13226.

In particular, FDA was fully aware of the concerns expressed by plaintiffs in this suit regarding the scope of the regulation's grandfather clause and the potential impact on small businesses. As noted above, the 1996 rule included a grandfather clause for situations in which a trade or brand name already appeared

on tobacco and nontobacco products sold in the United States on January 1, 1995. 21 C.F.R. § 897.16(a). Re-issuance of the rule more than a decade later raised questions about the appropriateness of retaining the January 1, 1995 date. *See* Exhibit C (Jan. 21, 2010 FDA letter to Member of Congress) (noting unique compliance challenges faced by small businesses).

Accordingly, on April 26, 2010, the Office of Management and Budget announced that "FDA is proposing to amend 21 CFR 1140.16(a) to revise the date on which cigarettes and smokeless tobacco products with trade or brand names that are on both a tobacco product and a nontobacco product would be allowed to continue the use of such trade or brand name under the re-issued 1996 final rule." Exhibit A. In this announcement, OMB explained that FDA intends to issue a Notice of Proposed Rulemaking in September 2010, with the comment period to close in October 2010. *Ibid*.

In Guidance published on May 4, 2010, FDA made clear that it does not intend to enforce the regulation under the terms of the original grandfather clause. Instead, pending agency action to reconsider the regulation, FDA's intention is not to enforce the regulation as long as the trade or brand name of the tobacco product was registered or the product was marketed before June 22, 2009, the date of the enactment of the Tobacco Control Act. *See* 75 Fed. Reg. 25271 (Exhibit A to plaintiffs' motion).

It is undisputed that plaintiffs' brands were marketed before June 22, 2009 and thus fall within the scope of the FDA's announced non-enforcement policy. *See* Pl. Mem. 9; *see also id*. at 5 n.3 & 6 n.4. On May 6, 2010, FDA's Chief Counsel wrote plaintiffs' counsel a letter stating that FDA has no intention of suddenly reversing course without notice prior to completion of the FDA's reconsideration of the rule. *See* Exhibit B. The letter explained that "[c]onsistent with its typical practice, FDA will not initiate an enforcement action that is contrary to the positions stated in the Guidance without first publishing in the Federal Register a notice of withdrawal of the Guidance and issuing a warning letter to the affected party." *Ibid*.

Nevertheless, later the same day, plaintiffs filed their motion for a preliminary injunction.

ARGUMENT

A. A preliminary injunction "is an extraordinary remedy afforded prior to trial at the discretion of the district court that grants relief *pendente lite* of the type available after the trial." *Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 345 (4th Cir. 2009). To obtain a preliminary injunction a plaintiff "must establish '[1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.'" *Id*. at

346 (quoting *Winter v. Natural Resources Defense Council*, 129 S. Ct. 365, 374 (2008)).

As the Fourth Circuit has observed, "[t]he 'likelihood of irreparable harm to the plaintiff' is the first factor to be considered" because the "basis of injunctive relief in the federal courts has always been irreparable harm and inadequacy of legal remedies.'" *Direx Israel, Ltd. v. Breakthrough Medical Corp*. 952 F.2d 802, 812 (4th Cir. 1991) (quoting *Samson v. Murray,* 415 U.S. 61, 88 (1974)). A failure to make a clear showing of irreparable harm "'is by itself a sufficient ground upon which to deny a preliminary injunction.'" *Ibid.* (quoting *Gelco Corp. v. Conniston Partners,* 811 F.2d 414, 418 (8th Cir. 1987)). Moreover, "'the required irreparable harm must be neither remote nor speculative, but actual and imminent.'" *Scotts Co. v. United Industries Corp*., 315 F.3d 264, 283 (4th Cir. 2002) *(quoting Direx,* 952 F.2d at 812). Only if the plaintiff "has made a strong showing that it will suffer irreparable harm if the injunction is denied," does a court proceed to "balance the likelihood of that harm against the likelihood of harm that would be suffered by the defendant." *Ibid*.[3]

[3] As the Fourth Circuit explained in *Real Truth About Obama*, 575 F.3d at 346-347, the framework set out in *Blackwelder Furniture Co. of Statesville v. Seilig Manufacturing Co*., 550 F.2d 189 (4th Cir. 1977), for evaluating a request for a preliminary injunction was superseded by the Supreme Court's decision in *Winter v. Natural Resources Defense Council*, 129 S. Ct. 365 (2008), which set out a more stringent standard for issuance of a preliminary injunction.

Plaintiffs here fail to establish the likely irreparable harm that is required for preliminary relief. They seek a preliminary injunction to enjoin enforcement of the trade or brand name regulation pending a final determination on the merits of their constitutional claims. They persist in that request even though FDA has made clear that it does not intend to enforce the regulation for products marketed before June 22, 2009, *see* 75 Fed. Reg. 25271, a category that indisputably includes plaintiffs' products. To the extent that plaintiffs face any risk of harm, it is remote and speculative.

Plaintiffs suggest that a preliminary injunction is necessary to guard against an abrupt change in enforcement policy. They speculate that FDA might "reverse[] its position" "at any time" and enforce the grandfather clause in the original regulation. Pl. Mem. 23; *see also* Exhibit D (May 11, 2010 letter from plaintiffs' counsel). These assertions fail to recognize that FDA's enforcement position is linked to its reconsideration of the grandfather clause of which plaintiffs complain. As discussed above, the Tobacco Control Act directed FDA to re-issue specified provisions of its 1996 rule in their original form, but also gave FDA authority to reconsider those regulations — after the reissuance — through rulemaking. As required by statute, FDA thus reissued the provision concerning use of brand names of nontobacco products. In so doing, however, FDA also recognized that concerns would be raised if the regulation were enforced

with the grandfather clause included in the 1996 rule without considering whether products registered at a later date should similarly be allowed. Accordingly, the Office of Management and Budget announced on April 26 that "FDA is proposing to amend 21 CFR 1140.16(a) to revise the date on which cigarettes and smokeless tobacco products with trade or brand names that are on both a tobacco product and a nontobacco product would be allowed to continue the use of such trade or brand name under the re-issued 1996 final rule." Exhibit A. FDA intends to issue a Notice of Proposed Rulemaking in September 2010, with the comment period to close in October 2010. *Ibid*.

Plaintiffs note that the Guidance states that it is nonbinding. Pl. Mem. 9. That language, however, is not unique to this Guidance; it routinely appears in FDA guidance and is required by statute. Congress has directed FDA to inform the public of its policies, practices, and views, including its interpretations of its own regulations, through the issuance of guidance. 21 U.S.C. § 371(h). That statute provides that guidance is not binding and requires that the guidance document itself "indicate [its] nonbinding nature." *Id*. § (h)(2).

After plaintiffs nonetheless expressed concern about this standard guidance language, FDA sought to further reassure them in the May 6, 2010 letter from FDA's Chief Counsel. As that letter explained, FDA will not make unannounced changes to the enforcement policy set forth in the Guidance. On the contrary,

"[c]onsistent with its typical practice, FDA will not initiate an enforcement action that is contrary to the positions stated in the Guidance without first publishing in the Federal Register a notice of withdrawal of the Guidance and issuing a warning letter to the affected party." Exhibit B. Indeed, the purpose of the Guidance to "provide[] clarifying information related to FDA's enforcement policy," 75 Fed. Reg. 25271, would be defeated if regulated parties reasonably feared that FDA might, without notice, "reverse[] its position" "at any time." Pl. Mem. 23.

The Guidance at issue here is of concern to many companies other than the plaintiffs in this suit. Plaintiffs declare that "in Virginia alone" there are 118 cigarette brands manufactured by 33 different small manufacturers that would be adversely affected by the grandfather clause in the original regulation. Pl. Mem. 27. None of these many similarly situated manufacturers have found it necessary to seek adjudication of a question currently being considered by FDA, much less to seek extraordinary relief after FDA has already made its position clear.

Whereas plaintiffs cannot establish any irreparable harm, issuance of an injunction would seriously compromise the effectiveness of FDA guidance. As explained above, guidance is a tool authorized by statute and routinely used by FDA to advise regulated industries of its enforcement policies. An injunction entered in the face of such guidance would incorrectly signal that guidance is meaningless and that industry members should instead file lawsuits seeking

injunctions. That, in turn, would burden the courts with premature and often ultimately unnecessary lawsuits. The harms caused by an injunction thus would extend well beyond this case and be flatly contrary to the public interest.

B. Plaintiffs mistakenly urge that FDA should have acted earlier to reconsider the regulation, asserting that "Congress directed the FDA to 'include such modifications to [the 1996 regulations] that the Secretary determines are appropriate in light of governing First Amendment case law, including the decision of the Supreme Court in *Lorillard Tobacco Co. v. Reilly*, [533 U.S. 525 (2001)]." Pl. Mem. 3 (quoting P.L. 111-31, § 102(a)(2)(E)).

Even if plaintiffs were correct, their assertion would not demonstrate irreparable harm that would justify a preliminary injunction. In any event, plaintiffs misread the statute. The bracketed language inserted into the statutory text significantly alters its meaning. Congress did not authorize FDA to modify "the 1996 regulations" as a whole prior to re-issuance. Instead, it authorized FDA to modify the provision of the 1996 rule that pertained to outdoor advertising. *See* 21 U.S.C. § 387a-1(a)(2)(E) (authorizing modifications to 21 C.F.R. § 897.30(b)). That regulation prohibited outdoor tobacco advertising within 1000 feet of a school or playground and was thus similar to the measure invalidated in *Lorillard*.

By contrast, Congress required that other provisions of the 1996 rule be reissued in "identical" form. 21 U.S.C. § 387a-1(a)(2). Congress directed FDA to

publish the rule in the Federal Register 270 days after the date of enactment of the Act. *See id*. § 387a-1(a)(1) & *id*. § 387 Note ("Modifications of deadlines for secretarial action"). Congress provided that the rule would take effect one year after the date of the Act's enactment. *See id*. § 387a-1(a)(2)(F). And Congress specified the manner in which the rule could be amended, by authorizing FDA to amend the rule through notice and comment rulemaking. *Id*. § 387a-1(a)(3), (4). FDA's authority to amend the rule is not limited to changes made in light of First Amendment case law; under ordinary rulemaking principles FDA also may take into account policy concerns such as the ones raised by plaintiffs, including the impact on small business.

Although plaintiffs allege that FDA's actions were "*ultra vires*," Complaint ¶ 112, the agency's actions comported exactly with these congressional directives. FDA reissued the original regulation on March 19, 2010, as required under the Tobacco Control Act, but also announced that it intends to amend that regulation through notice and comment rulemaking. FDA explained that it does not intend to enforce the regulation during the pendency of the rulemaking, an enforcement decision that falls well within the agency's discretion.

This case thus bears no resemblance to the case on which plaintiffs rely, *United States v. Stevens*, No. 08-769, 2010 WL 1540082 (S. Ct. April 20, 2010). *See* Pl. Mem. 10, 19-20. In *Stevens*, the Court held that an unconstitutional statute

could not be saved by the Attorney General's commitment to enforce the statute only in ways that would not violate the First Amendment. The Attorney General had no authority to amend the statute, and the Court explained that it "would not uphold an unconstitutional statute merely because the Government promised to use it responsibly." *Stevens*, 2010 WL 1540082, *13. The Court observed that the statute was not susceptible to a narrowing construction that would have avoided the constitutional issue. *Ibid*.

In sharp distinction, this case involves a rule that FDA is expressly authorized to amend and that FDA has stated that it intends to amend (while also stating that it does not intend to enforce the regulation in the interim).

C. Plaintiffs are asking the Court to preliminarily enjoin the enforcement of a regulation that is not being enforced and that is under agency reconsideration. Plaintiffs thus ask the Court to enmesh itself in the consideration of constitutional claims that are plainly not ripe (and that likely never will become ripe) for adjudication. A claim "is not ripe for adjudication," when, as in this case, "it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998). Even in the First Amendment context, a plaintiff must "demonstrate a live dispute involving the actual or threatened application of [a statute or policy] to bar particular speech." *Renne v. Geary*, 501 U.S. 312, 320 (1991). These principles apply with particular

force when the administrative agency responsible for statutory enforcement is already considering the issue presented. In such circumstances, a court will not interfere until the agency's process is completed and "its effects felt in a concrete way by the challenging parties." *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-149 (1967); *see also Virginia Society for Human Life, Inc. v. FEC*, 263 F.3d 379, 389-390 (4th Cir. 2001). Because there is no ripe controversy here, plaintiffs have no likelihood of success on the merits.

In sum, plaintiffs have not satisfied the first and most basic requirement for a preliminary injunction — a clear showing that preliminary relief is required to avoid irreparable harm. Ignoring the administrative process that may make it unnecessary to resolve their First and Fifth Amendment contentions, they ask the Court to issue advisory rulings on claims that are not now ripe and may never require adjudication. That request should be denied.

CONCLUSION

Plaintiffs' motion for a preliminary injunction should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 12th day of May, 2010 I have electronically filed the foregoing pleading with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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